

**REMARKS****The Amendments**

Claim 1 is amended for clarification purposes to address the 35 U.S.C. § 112 rejection, as discussed below. These amendments do not narrow the scope of the claims. Claim 1 is also amended to remove the “rutin” recitation from the claims to avoid the newly cited prior art, as discussed below.

To the extent that the amendments avoid the prior art or for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to Applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

**The Rejection under 35 U.S.C. § 112, second paragraph**

The rejection of claims 1-10, 12-14 and 26 under 35 U.S.C. § 112, second paragraph, is respectfully traversed.

As to the “synergistically effective” term, the rejection is rendered moot by the removal of such language. The synergistic effect is inherent in the compositions and, thus, need not be recited in the claim.

The claims have been amended for clarity as to the purity aspect, although the same meaning is intended. Applicants had intended – and believed it was clear – that the previous language meant the composition was purified so that it contained essentially no flavones or flavonoids other than those already specifically recited, i.e., other than isoquercitrin, and the

other component selected from the group consisting of 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acacetin, eriodictyol, quercitrin, catechol, hesperitin, a glycoside of any of the above other components, a vitamin, a carotene and ascorbic acid. It is true that the isoquercitrin and other components include flavones and flavonoids but the intention was to essentially exclude any additional flavones or flavonoids. As is apparent from the rejection, the claims were not interpreted in this manner. Thus, they have been amended again in the hope of making this more clear. For example, as discussed more fully below, the claims would literally exclude a composition which contained any significant amount of rutin or glycoside thereof because rutin is not included in the list of specifically included compounds. Applicants do not understand the statement in the Office Action that “any detectable flavone or flavonoids is a purified flavone.” If the composition contains any significant amount of a flavone or flavonoid component not included in those specifically listed, then the composition would not fall within the literal definition of the composition.

For the above reasons, it is urged that the rejection under 35 U.S.C. § 112 be withdrawn.

#### **The Objection to Claim 26**

Contrary to the allegation in the Office Action, claims 12 and 26 are not identical. Claim 12 recites an amount of 0.01 - 10%, whereas, claim 26 recites an amount of 0.1 - 10%. The objection should be withdrawn.

**The Rejection under 35 U.S.C. § 102**

The rejection of claims 1 and 8 under 35 U.S.C. § 102, as being anticipated by Toyo Seito (JP 07-002677; hereinafter “JP ‘677”) is respectfully traversed.

JP ‘677 teaches compositions for treating hair loss and graying which “are characterized by containing alpha-glucosylated rutin.” See the first sentence after the Summary of the Invention on page 2 of the translation. The compositions may also contain other flavonoids selected from rutin, quercetin, isoquercitrin, hesperidin, naringin, methyl hesperidins and glucosylated versions thereof. Because the ‘677 compositions require a glucosylated rutin, they are excluded from the instant compositions. The instant claims recite a composition which contains essentially no flavones or flavonoids other than the isoquercitrin and a component selected from the group consisting of 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acacetin, eriodictyol, quercitrin, catechol, hesperitin, a glycoside of any of the above other components, a vitamin, a carotene and ascorbic acid. Rutin is a flavonoid as shown in the attached excerpt from the International Dictionary of Medicine and Biology, vol. III (1986). Glucosylated rutin is a glycoside of rutin. Thus, since it is not included in the list of compounds included in applicants’ claim 1, it is a glycoside of a flavonoid essentially excluded by instant claim 1.

Because the JP ‘677 composition contains a significant amount of a component essentially excluded from the instant claimed composition, JP ‘677 cannot anticipate the instant claims and the rejection under 35 U.S.C. § 102 should be withdrawn. A disclosure that requires a particular element as an essential ingredient neither anticipates nor renders obvious claims requiring the substantial absence of such element. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding the term “essentially,” it is urged that its meaning as used in the instant claims would be evident to one of ordinary skill in the art and in view of the law. “Essentially” has a recognized meaning in the law (see, e.g., wealth of case law regarding the “consisting essentially of” term). Thus, it would be clear that if a composition contains “essentially no” amount of a certain component(s) it can only contain amounts of such component(s) which have no discernible effect on the composition, e.g., ineffective trace amounts. Although the term “essentially” does not provide a specific number on the amount, such is not necessary for the purposes of 35 U.S.C. § 112, see Marosi, cited above. The “essentially” term, as used here, is clearly sufficient to distinguish the JP ‘677 disclosure wherein the glycosylated rutin is the principal characterizing feature of the prior art invention.

#### **The Rejection under 35 U.S.C. § 103**

The rejection of claims 1-10, 12-14 and 26 under 35 U.S.C. § 103, as being obvious over JP ‘677 in view of Lanzendorfer (WO 96/18381), Fujirebio (JP 04234320) and Bean (U.S. Patent No. 4,132,782) is respectfully traversed.

As stated above in citing the Marosi decision, a disclosure requiring a particular component as an essential ingredient cannot render obvious claims essentially excluding such component. There would clearly be no motivation to one of ordinary skill in the art to modify the JP ‘677 invention by essentially removing the glycosylated rutin component. In the absence of such motivation, JP ‘677 clearly cannot suggest the claimed invention which essentially excludes the glycosylated rutin component.

The secondary references of Lanzendorfer, Fujirebio and Bean also do not teach or suggest modifying the JP ‘677 compositions to remove the glycosylated rutin component. To the contrary, Lanzendorfer discloses that glycosylated rutin is a preferred component of its

mixtures, see, col. 5, lines 60-62. These references were relied upon in the Office Action for, allegedly, suggesting modifying the JP '677 compositions to add a UV filter compound and to apply such compositions topically. Even if the references suggested this, they would still not result in applicants' invention, however, because such modified compositions would still require the glycosylated rutin component.

Lanzendorfer provides a very broad teaching of compositions containing multiple types of components and a vast scope of particular components within each type of component. Amongst the components suggested are flavonoids. Lanzendorfer mentions many specific flavonoids, e.g., at col. 5, line 23, to col. 6, line 4, but there is no specific mention of isoquercitrin. Contrary to the statement in the Office Action, it is not seen where Lanzendorfer mentions quercitrin derivatives or otherwise specifically points to isoquercitrin. Obviously, there is also no mention or suggestion of isoquercitrin together with other particular flavones or flavonoids in a purified form which excludes other flavonoids or that isoquercitrin has particular advantages over other flavonoids.

Bean teaches a mountain ash berry extract composition for a utility similar to the Lanzendorfer compositions. The composition contains isoquercitrin but also contains other various flavonols. It is admitted in the reference that it is not known what component(s) of the extract give the composition its desired properties. Thus, the reference provides no motivation to one of ordinary skill in the art to isolate any of the components, including isoquercitrin, from any of the other components. Contrary to the statement in the Office Action, Bean does not teach that isoquercitrin has antiviral activity. Bean itself states that it does not know which component(s) of its compositions is the active agent.

Fujirebio teaches isoquercitrin as an anti-HBV agent. It does not disclose a combination of isoquercitrin and a component selected from the group consisting of 5-

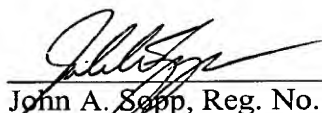
ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acacetin, eriodictyol, quercitrin, catechol, hesperitin, a glycoside of any of the above other components, a vitamin, a carotene and ascorbic acid.

It is respectfully submitted that combined teachings of JP '677, Lanzendorfer, Fujirebio and Bean, as a whole, would not have suggested the claimed invention to one of ordinary skill in the art. The secondary references fail to suggest modifying JP '677 in a manner resulting in the claimed invention and do not otherwise suggest the claimed invention. Thus, the rejection under 35 U.S.C. § 103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

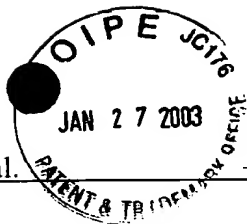


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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Three times Amended) A pharmaceutical or cosmetic composition

comprising:

a carrier, ~~and synergistically effective amounts of~~

isoquercitrin, and another

a component which is selected from the group consisting of 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acacetin, eriodictyol, quercitrin, catechol, hesperitin, ~~rutin~~, a glycoside of any of the above other components, a vitamin, a carotene ~~or~~ and ascorbic acid, ~~and where~~

wherein the composition ~~is substantially of purified~~ contains essentially no flavones, flavonoids or glycosides thereof other than isoquercitrin or the other above-listed components.

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of the musculature of a gravid uterus at the site of a previous uterine scar.

**intracapsular rupture** A tubal ectopic pregnancy in which the amniotic sac ruptures and the embryo is expelled into the lumen of the fallopian tube.

**rupture of membranes** The breaking or tearing of the amniotic sac, leading to leakage of amniotic fluid through the uterine cervix and into the vagina.

**premature rupture of membranes** The tearing of the amniotic sac prior to the onset of labor.

**prolonged rupture of membranes** The tearing of the amniotic sac 24 or more hours prior to the onset of labor.

**spontaneous rupture** The disruption of the musculature of a gravid uterus in the absence of any trauma. The uterus may or may not have scarring from a previous incision.

**spontaneous rupture of membranes** Rupture of the amniotic sac without use of digital pressure or instruments.

**traumatic rupture** The disruption of the musculature of a gravid uterus with or without previous scarring due to the use of oxytocic agents, intrauterine manipulations, external uterine pressure, or instrumental delivery of the fetus.

**rupture of the tympanic membrane** Perforating injury of the tympanic membrane caused by trauma, such as that resulting from temporal bone fractures (usually longitudinal fractures), blows on the ear (particularly from the flat of the hand), blast injury (especially from exposure to bomb blast), and injury from foreign bodies introduced into the external auditory meatus. Perforations caused by otitis media are not really ruptures. Also called *myringorupture* (rarely used).

**ruptured** Forcibly disrupted, as tissue or the wall of a hollow organ; herniated.

**RUQ** right upper quadrant (of abdomen).

**rush / peristaltic rushes** Rapid waves of intestinal muscular contraction causing propulsion of intestinal contents.

**Russell** [Alexander Russell, English pediatrician, flourished 20th century] 1 Russell syndrome. See under DIENCEPHALIC SYNDROME OF INFANCY. 2 See under DWARF. 3 Silver-Russell syndrome. See under SYNDROME.

**Russell** [Frederick Fuller Russell, U.S. pathologist, 1870-1960] Russell's double sugar agar. See under AGAR.

**Russell** [Patrick Russell, English physician active in Syria, 1727-1805] 1 See under VIPER. 2 Russell's viper venom. See under VENOM.

**Russell** [R. Hamilton Russell, Australian surgeon, flourished early 20th century] See under TRACTION.

**Russell** [William Russell, Scottish physician, 1852-1940] Russell corpuscles. See under RUSSELL BODIES.

**Russell** [William James Russell, English chemist, 1830-1909] Russell effect. See under PHOTECHEMICAL EFFECT.

**Rust** [Johann Nepomuk Rust, Austrian surgeon, 1775-1840] See under DISEASE, PHENOMENON, SIGN.

**rust** 1 A reddish brown coat of ferric oxide or ferric hydroxide formed on iron or steel surfaces exposed to moisture. 2 To undergo oxidation into rust. 3 A parasitic fungus of the class Basidiomycetes, subclass Teliomycetidae, order Uredinales. A rust fungus seasonally produces spores of several types on leaves and/or stems of vascular plants. The clusters of spores in summer are the color of iron rust.

**black rust** A late summer stage of graminaceous rusts.

**red rust** The midsummer stage of graminaceous rusts.

**white rust** A plant disease caused by various species of the phycomycete genus, *Albugo*. This disease is normally characterized by the formation of white or yellowish epidermal blisters or pustules. A wide variety of plant species may be susceptible to this disease.

**rut** [Middle English *rutte*, from Old French *ruit* a noise, from Late L *rugitus* a roaring, from L *rugitus*, past part. of *rugire* to roar] 1 A time of sexual activity in certain male animals such as deer and elephants. It is during this period that spermatogenesis and mating occur. 2 The roaring noises made by certain animals during the mating season.

**ruthenium** Element number 44, having atomic weight 101.07. Ruthenium is a hard, white metal. It occurs native along with platinum and combined in various ores. It resembles osmium in that it spontaneously (under certain conditions) forms a highly toxic tetroxide, which is explosive. The metal is used as a catalyst and an alloying element. Symbol: Ru

**ruthenium red** Any of several compounds formed by treating ruthenium salts in solution with ammonia and oxygen. They contain several ruthenium atoms, in different oxidation states, linked through oxygen atoms and carrying ammonia molecules as ligands.

**Rutherford** [Lord Ernest Rutherford, New Zealand-born British physicist, 1871-1937] See under ATOM, SCATTERING.

**rutherford** [after Sir Ernest Rutherford, New Zealand-born British physicist, 1871-1937] A unit of radioactivity equal to the quantity of a radioactive nuclide which undergoes  $10^6$  disintegrations per second;  $10^6$  disintegrations per second = 1 megabecquerel. An obsolete unit. Symbol: Rd, rd

**rutidosis** RHYTIDOSIS.

**rutilism** [L *rutil(us)* red, bright red + -ISM] The state of possessing red hair.

**rutin**  $C_{27}H_{30}O_{16}$ . A bioflavonoid found in buckwheat. Also called *phytomelin*, *rutoside*.

**rutoside** RUTIN.

**Ruysch** [Frederik Ruysch, Dutch anatomist, 1638-1731] 1 Ruysch disease. See under CONGENITAL MEGACOLON. 2 See under MUSCLE, TUBE. 3 Ruysch tunic, Ruysch membrane, tunica ruyschiana. See under LAMINA CHORIOCAPILLARIS. 4 Ruysch veins. See under RETZIUS VEINS. 5 Ruysch veins. See under VENAE VORTICOSAE.

**RV** residual volume.

**RVH** right ventricular hypertrophy.

**-ry** -ERY.

**ryanodine**  $C_{25}H_{35}NO_9$ . An alkaloid isolated from the stem and root of *Ryania speciosa*. It has been used as an insecticide and a contact and stomach poison to control agricultural pests.

**rye** [Middle English, from Old English *ryge*] *Secale cereale*, an annual cereal grass of the Gramineae family.

**spurred rye** Rye infected by ergot and having the characteristic shape of the sclerotia extending from the head of the rye plant.

**Ryle** [John Alfred Ryle, English physician, 1889-1950] See under TUBE.